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MAR 19 2009

510(K) SUMMARY

Subject 510(k) Number ***K090128***

Sponsor

Core Essence Orthopaedics, Inc.

575A Virginia Drive
Fort Washington, PA 19034

FDA Establishment Registration Number

3006283823

Official Contact

Richard Washburn, President
Core Essence Orthopaedics, Inc.
575A Virginia Drive
Fort Washington, PA 19034
Phone - (215) 310-9534
Fax - (609) 482-4957

Proprietary Name

TAC-tite™ Suture Anchor System

Common Name

Suture Anchor

Classification Name and Reference

Sec. 888.3040 Smooth or threaded metallic bone fixation fastener

Regulatory Class

Class II

Device Product Code/Subsequent Code

(Panel 87) MBI/GAT

Date Prepared

18 September, 2012 (revised)

Brief Description of Device

The TAC-tite™ Suture Anchors are available in 5.5mm and 7.0mm diameters.

The TAC-tite™ Suture Anchors are available with a threaded titanium (ASTM F136/ ISO 5832-3) anchor body (that provides a self drilling and self tapping thread). The TAC-tite™ anchor eyelet is designed to accept size 2 (USP) nonabsorbable UHMW polyethylene UltraFibre™ sutures. A single use driver and handpiece delivers the preloaded anchor into the bone.

The TAC-tite™ Suture Anchor will be provided sterile for single use application.

Indications for Use

TAC-tite™ Suture Anchors are intended to secure soft tissue to bone of:

The Shoulder:
- Bankart Repair
- SLAP Lesion Repair
- Acromio-Clavicular Separation
- Roatator Cuff Repair
- Capsule Repair
- Biceps Tenodesis
- Deltoid Repair

The Elbow:
- Ulnar or Radial Collateral Ligament Reconstruction
- Bicep Tendon Reconstruction
- Tennis Elbow Repair

The Hand and Wrist:
- Scapholunate Ligament Reconstruction
- Ulnar / Radial Collateral Ligament Reconstruction
- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

The Ankle and Foot:
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair / Reconstruction
- Hallux Valgus Reconstruction
- Mid and Rear Foot Reconstruction

Basis for Substantial Equivalence

The substantial equivalence of the TAC-tite™ Suture Anchors is based on the equivalence in intended use, materials, operational principals, and indications to the reNOVO Suture Anchors covered by K071520.

END OF 510(K) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Core Essence Orthopaedics, Inc.
% Mr. Richard T. Briganti
Engineering Principal
575A Virginia Drive
Fort Washington, PA 19034

AUG 13 2012

Re: K090128
Trade/Device Name: TAC-tite™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, GAT
Dated: February 17, 2009
Received: February 19, 2009

Dear Mr. Briganti:

This letter corrects our substantially equivalent letter of March 19, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Statement of Indications for Use

510 (K) NUMBER IF KNOWN: K090128

MANUFACTURER: Core Essence Orthopaedics, Inc.

DEVICE NAME: TAC-tite™ Suture Anchors

TAC-tite™ Suture Anchors are intended to secure soft tissue to bone of:

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- Hallux Valgus Reconstruction
- Mid and Rear Foot Reconstruction

Prescription Use XX **and/or** **Over-the-Counter Use** NO

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K Arundi

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

for

510(k) Number K090128